MAY 3 0 2001

K010716

510(k) SUMMARY

Val Med's Val Lux 600 Surgical Light

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Val Med Corp.
4800 NW Saltzman Road
Portland, Oregon 97229
Telephone: (503) 614-1106
Facsimile: (503) 614-1109

Contact Person: Darko Spoljaric
Vice President

Date Prepared: March 9, 2001

Name of Device and Name/Address of Sponsor

Val Med Corp.
4800 NW Saltzman Road
Portland, Oregon 97229
Telephone: (503) 614-1106
Facsimile: (503) 614-1109

Common or Usual Name

Surgical Lamp

Classification Name

Ceiling Mounted Surgical Lamp

Predicate Devices

Hill-Rom, Inc.'s BrightStar©
American Sterilizer Co.'s Quantum©, SQ240
Getinge/Castle, Inc. OptiView©, 500 series

Intended Use / Indications for Use

The Val Lux 600 and each of its predicate devices are intended to provide illumination of the surgical field or the patient. Thus, the Val Lux 600 has the same intended use as the predicate devices.

The Val Lux 600 is indicated to eliminate shadows and reduce reflected heat with color corrected high intensity light. The OptiView© is indicated to be used to illuminate surgical procedures with color corrected light and heat filtering (IR). The OptiView© is also indicated to eliminate shadows and to penetrate deep cavity wounds with adequate lighting. Thus, the Val Lux 600 has very similar indications for use as the OptiView©.

Performance Data

The Val Lux 600 complies with the following standards:

- EEC 60601-1: MEDICAL ELECTRICAL EQUIPMENT, Part 1: General requirements for safety (IEC 60601-1:1988 A1:1991 and A2:1995), except for the inapplicable requirements, and UL2601-1 MEDICAL ELECTRICAL EQUIPMENT, Part 1: General requirements for safety (UL2601-1: Second Edition)

- IEC 60601-1-2: Electromagnetic Compatibility – Requirements and tests (EN60601-1:1990, A1:1993, A11:1993, A12, and A13:199)

- IEC 60601-2-41 Particular Requirements for the Safety of Surgical Luminaries and Luminaries for Diagnosis

Technological Characteristics

The Val Lux 600 lighting system consists of 60 cm diameter light head(s) and a center-mounted suspension system with 360-degree rotation positioning. The suspension system can support single, dual, and triple lightheads.

Substantial Equivalence

The Val Lux 600 has the same intended use and very similar indications for use and technological characteristics as its predicate, ceiling mounted surgical lamps: Hill-Rom, Inc.'s BrightStar©; American Sterilizer Co.'s Quantum©, SQ240; Getinge/Castle, Inc. OptiView©, 500 series. The minor differences in Val Lux 600's, maximum illumination at one meter and

illumination area do not raise any new issues of safety or effectiveness. Therefore, the Val Lux 600 is substantially equivalent to its predicate, ceiling mounted surgical lamps.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 3 0 2001

Val Med Corporation
c/o Mr. Howard Holstein
Hogan & Hartson L.L.P.
Columbia Square
555 Thirteenth Street, NW
Washington, D.C. 20004

Re: K010716
Trade/Device Name: Val Med Corp. Val Lux 600 Surgical Lamp
Regulation Number: 878.4580
Regulatory Class: II
Product Code: FSY
Dated: March 9, 2001
Received: March 9, 2001

Dear Mr. Holstein:

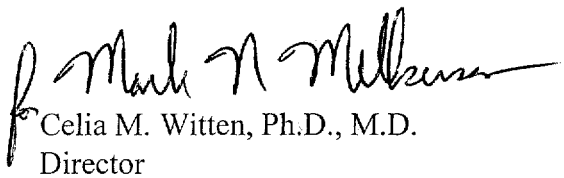
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K010716

Device Name: **Val Med Corp. Val Lux 600 Surgical Lamp**

Indications for Use:

The Val Lux 600 Series Central Mounted Surgical Light is intended to provide illumination of the surgical field or the patient. It is indicated to eliminate shadows and reduce reflected heat with color corrected high intensity light.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 C.F.R. 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)

for Mark N. Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010716